

Parecoxib Juno

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I given Parecoxib Juno?

Parecoxib Juno contains the active ingredient parecoxib sodium. Parecoxib Juno is used for the prevention and treatment of pain. It can be used to relieve pain and reduce inflammation (swelling and soreness) which may occur after surgery. Although Parecoxib Juno can relieve the symptoms of pain and inflammation, it will not cure your condition.

For more information, see Section [1. Why am I given Parecoxib Juno?](#) in the full CMI.

2. What should I know before I am given Parecoxib Juno

Do not use if you have ever had an allergic reaction to Parecoxib or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Parecoxib Juno?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Parecoxib Juno and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will I be given Parecoxib Juno?

Your doctor will decide how much Parecoxib Juno you may need. The usual recommended dose is a single 40 mg injection. Your doctor may adjust the dosage you are given depending on your condition.

Parecoxib Juno will be given to you by your doctor. It is diluted and given by injection into a vein through an intravenous line or into a muscle.

More instructions can be found in Section [4. How will I be given Parecoxib Juno?](#) in the full CMI.

5. What should I know while using Parecoxib Juno?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist, or pharmacist you visit that you are using Parecoxib Juno.
Things you should not do	<ul style="list-style-type: none">Do not take other medication unless your doctor is aware of it.
Driving or using machines	<ul style="list-style-type: none">This medication may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

For more information, see Section [5. What should I know while using Parecoxib Juno?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. Ask your doctor or pharmacist if you have any further questions about side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Parecoxib Juno

Active ingredient: *Parecoxib sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Parecoxib Juno. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Parecoxib Juno**

Where to find information in this leaflet:

- [1. Why am I given Parecoxib Juno?](#)
- [2. What should I know before I am given Parecoxib Juno?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given Parecoxib Juno?](#)
- [5. What should I know while using Parecoxib Juno?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I given Parecoxib Juno?

Parecoxib Juno contains the active ingredient parecoxib sodium.

This medicine belongs to a group of medicines called coxibs. These medicines work by relieving pain and inflammation.

Parecoxib Juno is used for the prevention and treatment of pain. It can be used to relieve pain and reduce inflammation (swelling and soreness) which may occur after surgery.

Although Parecoxib Juno can relieve the symptoms of pain and inflammation, it will not cure your condition.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

Parecoxib Juno is an injection. Only a doctor or nurse can give the injection.

This medicine is available only with a doctor's prescription

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children.

2. What should I know before I am given Parecoxib Juno?

Warnings

Do not use Parecoxib Juno if you are allergic to:

- Parecoxib sodium, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- Valdecoxib

- Sulphonamides, a group of medicines which include, for example, certain antibiotics (if you are not sure whether you are taking one of these medicines ask your doctor or nurse).

Some of the symptoms of an allergic reaction to Parecoxib Juno may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- swelling, blistering or peeling of the skin.

These symptoms may be severe if you are allergic to Sulphonamides or to any of the ingredients listed at the end of this leaflet

Ask your doctor or nurse if any of this applies to you.

You must not be given Parecoxib Juno if you have had an attack of asthma, hives, itching, skin rash or a runny nose after taking aspirin or Non- Steroidal Anti-Inflammatory Drugs (NSAIDs, medicines used to treat pain and inflammation), including other Coxib medicines.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or an NSAID.

If you are not sure if you are taking any of these medicines, ask your doctor or nurse.

If you are allergic to aspirin or NSAIDs, including other Coxib medicines and use Dynastat, these symptoms may be severe.

You must not be given Parecoxib Juno if you are about to undergo heart or blood vessel surgery. You should not be given Parecoxib Juno if you have had any of the following medical conditions. Your doctor or nurse needs to know if you have ever had:

- heart disease
- a heart attack
- a stroke
- severe liver problems.

If you are not sure whether you should be given this medicine, talk to your doctor.

Check with your doctor if you:

- have allergies to any other medicines including aspirin or other NSAID medicines, including other Coxib medicines.
- any other substances, such as foods, preservatives or dyes.

Your doctor needs to know about all your medical conditions, especially if you have any of the following medical conditions:

- kidney or liver problems
- heart problems, heart surgery, heart failure, heart attack or other blood vessel disease
- stroke
- diabetes
- high cholesterol levels
- high blood pressure
- fluid retention or if you are receiving diuretic treatment
- dehydration
- asthma or other allergic conditions
- skin problems with symptoms such as swelling, blistering, peeling, itching, reddening or some other abnormality
- peptic ulcer i.e. stomach or duodenal ulcer.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Related medicines, NSAIDs, have been associated with reversible infertility in some women.

Use of NSAIDs in early pregnancy can increase the risk of spontaneous abortion.

Use of Parecoxib Juno during pregnancy is not recommended as it may affect your developing baby.

Your doctor will discuss with you the benefits and risks of using it.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Parecoxib Juno passes into breast milk, therefore, breastfeeding should be discontinued during treatment with Parecoxib Juno

Your doctor and nurse need to know if you are a smoker or drink alcohol.

Your doctor and nurse need to know if you currently have an infection.

If you are given Parecoxib Juno while you have an infection, it may hide some of the signs of an infection. If you have not told your doctor and nurse about any of the above, tell them before you are given Parecoxib Juno.

3. WHAT IF I AM TAKING OTHER MEDICINES?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Your doctor and nurse need to know if you are taking any medicines used to treat high blood pressure or other heart problems. These include ACE inhibitors, angiotensin receptor antagonists, beta blockers and diuretics (also called fluid or water tablets).

These medicines can cause kidney problems if taken at the same time as you receive Parecoxib Juno.

Your doctor and nurse need to know if you are taking any of the following:

- aspirin, salicylates or other NSAID medicines used to treat pain, inflammation or swelling
- corticosteroids, medicines used to suppress the immune system or reduce inflammation
- selective serotonin reuptake inhibitors, medicines used for depression
- warfarin or similar medicines including Eliquis (apixaban), Xarelto (rivaroxaban), Pradaxa (dabigatran) or antiplatelet medicines that are used to prevent or stop blood clots from forming
- lithium, a medicine used to treat some types of depression
- some medicines used to treat diabetes
- methotrexate, a medicine used to treat arthritis and some cancers
- ciclosporin, a medicine used to suppress the immune system
- fluconazole and ketoconazole used to treat fungal infections.

Your doctor and nurse have more information on medicines to be careful with or avoid while using Parecoxib Juno

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Parecoxib Juno.

4. How will I be Parecoxib Juno given?

How you are given Parecoxib Juno

Your doctor will decide how much Parecoxib Juno you need. The usual recommended dose is a single 40 mg injection. Your doctor may adjust the dosage you are given depending on your condition.

Parecoxib Juno will be given to you by your doctor. It is diluted and given by injection into a vein through an intravenous line or into a muscle.

Ask your doctor if you want more information about the dose of Parecoxib Juno and how it is given

If you are given too much Parecoxib Juno

As your doctor will supervise how much Parecoxib Juno you are given, you are unlikely to have an overdose.

If you are given too much Parecoxib Juno, you may feel tired, drowsy or experience vomiting, have stomach pains or other abdominal problems.

If you think you have been given too much Parecoxib Juno:

You should immediately:

- Tell your doctor or nurse immediately, or
- phone the Poisons Information Centre (by calling **13 11 26 in Australia or 0800 764 766 [0800 POISON]** in New Zealand), or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Parecoxib Juno?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking Parecoxib Juno.
- Check with your doctor or pharmacist before you start to take any other medication.

Things you should not do

- Do not take any other medication unless your doctor is aware of it.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Parecoxib Juno affects you.

This medicine may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Looking after your medicine

Parecoxib Juno will be stored in the pharmacy or in the ward. The powder for injection is kept in a cool, dry place, protected from light, where the temperature stays below 30°C.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal-related <ul style="list-style-type: none"> • stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion, cramps • constipation, diarrhoea, pain in the stomach, wind, bloating 	Speak to your doctor if you have any of these less serious

Oral-related <ul style="list-style-type: none"> • sore throat • swollen and sore gums • inflammation and pain after a tooth extraction Pain-related <ul style="list-style-type: none"> • back pain • earache Other <ul style="list-style-type: none"> • changes in blood pressure • dizziness or light-headedness due to low blood pressure • feeling numb (your skin may lose sensitivity to pain and touch) • increased sweating • passing less urine than normal Mental or emotional-related <ul style="list-style-type: none"> • Trouble sleeping • Irritability 	side effects and they worry you.
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Serious side effects

Serious side effects	What to do
Allergy-related <ul style="list-style-type: none"> • a skin rash, including hives, raised red, itchy spots • blistering and bleeding in the lips, eyes, mouth, nose and genitals • swelling, blistering or peeling of the skin, which may be accompanied by fever, chills, headache, sore throat, diarrhoea, aching joints and muscles • swollen glands e.g. under armpit or neck • any other signs of allergic reaction such as wheezing, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing Other <ul style="list-style-type: none"> • a slow heartbeat • a severe or persistent headache, fever, stiff neck, sensitivity to light and vomiting • bleeding or bruising more easily than normal, reddish or purplish blotches under the skin • any signs of anaemia, such as tiredness, being short of breath, and looking pale • an unusual weight gain or loss of appetite • unusual stomach sounds swelling of lips and tongue • severe stomach or throat pain • joint pain, muscle weakness • you are vomiting blood or having black sticky bowel motions 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

<ul style="list-style-type: none"> • any infection of, or discharge from, any wounds complications with skin healing after operations • Injection site pain or reaction • Yellowing of the skin or eyes (jaundice) • a dry mouth, feeling of thirst and needing to urinate more often • feeling faint or collapse, have shortness of breath, feel tired 	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems In Australia, or at www.medsafe.govt.nz/safety/report-a-problem.asp in New Zealand.

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Parecoxib Juno contains

Active ingredient (main ingredient)	Parecoxib sodium
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Sodium phosphate-dibasic • Phosphoric acid • Sodium hydroxide

Do not take this medicine if you are allergic to any of these ingredients.

What Parecoxib Juno looks like

Parecoxib Juno is a white to off-white powder supplied in a single use glass vial.

AUST R 282354

Who distributes Parecoxib Juno

Juno Pharmaceuticals Pty Ltd
15 – 17 Chapel Street,
Cremorne,
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Australia

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